

K070561

Teleflex Medical
KMedic® Internal/External Fixation Devices
Abbreviated PreMarket Notification (510(k)) Submission

MAY 25 2007

SECTION 5 - 510(K) SUMMARY

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS KMedic® Internal/External Fixation Devices

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical
2345 Waukegan Road
Bannockburn, IL 60015 USA
Phone: 847-572-8002
Fax: 847-572-8001

B. Contact Person

Lori Hays
Director, Regulatory Affairs

C. Date Prepared

February 22, 2007

D. Device Name

Trade Name: KMedic® Internal/External Fixation Devices

Common Name: Internal/External Fixation Devices

Classification Name: Smooth or threaded metallic bone fixation fastener

Product Code: HTY, JDW, and HWC

Regulation Number: 21 CFR § 888.3040

Class: II

E. Device Description

The KMedic® Internal/External Fixation Devices consist of various fixation pins and wires for use in unilateral internal/external fixation. The various lengths, sizes and end configurations are offered to accommodate various patient anatomies, injuries and/or conditions, and physician preference. All KMedic® Internal/External Fixation Devices included in this submission are manufactured from stainless steel and will be offered non-sterile.

F. Indications for Use

The KMedic® Internal/External Fixation Devices are non-sterile, single-use; internal/external fixation devices intended to be used for unilateral internal/external fixation in the treatment of bone conditions including limb lengthening, osteotomies; arthrodesis, fracture fixation and other bone conditions amenable to treatment by use of the internal/external fixation modality.

G. Substantial Equivalence

The device is similar in intended use, materials, design, and performance characteristics to the Zimmer K-Wires, Steinmann Pins and Schanz Screws (Pre-Amendment). The determination of substantial equivalence for this device was based on a detailed device description and conformance with voluntary standards.

H. Summary of Testing

The KMedic® Internal/External Fixation Devices comply with ASTM F138-03 "Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)" and ASTM F366-04 "Standard Specification for Fixation Pins and Wires".



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Teleflex Medical
c/o Ms. Daphne D. Maurer
Vice President, Regulatory Affairs
2345 Waukegan Road
Suite 120
Bannockburn, Illinois 60015

MAY 25 2007

Re: K070561

Trade/Device Name: KMedic® Internal/External Fixation Devices
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener.
Regulatory Class: Class II
Product Code: HTY, JDW, and HWC
Dated: May 3, 2007
Received: May 4, 2007

Dear Ms. Maurer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Teleflex Medical
KMedic® Internal/External Fixation Devices
Abbreviated PreMarket Notification (510(k)) Submission

SECTION 4 - INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K070561

Device Name: KMedic® Internal/External Fixation Devices

Indications for Use:

The KMedic® Internal/External Fixation Devices are non-sterile, single-use; internal/external fixation devices intended to be used for unilateral internal/external fixation in the treatment of bone conditions including limb lengthening, osteotomies, arthrodesis, fracture fixation and other bone conditions amenable to treatment by use of the internal/external fixation modality.

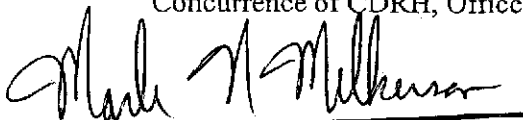
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number

K070561

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